

§ 1116.3

functional design, construction, warnings or instructions related to safety, function, user population, or other characteristics which could affect the product's safety related performance. (15 U.S.C. 2084(e)(2))

(1) The *functional design* of a product refers to those design features that directly affect the ability of the product to perform its intended use or purpose.

(2) The *construction* of a product refers to its finished assembly or fabrication, its materials, and its components.

(3) *Warnings or instructions related to safety* include statements of the principal hazards associated with a product, and statements of precautionary or affirmative measures to take during the use, handling, or storage of a product, to the extent that a reasonable person would understand such statements to be related to the safety of the product. Warnings or instructions may be written or graphically depicted and may be attached to the product or appear on the product itself, in operating manuals, or in other literature that accompanies or describes the product.

(4) The *function* of a product refers to its intended use or purpose.

(5) *User population* refers to the group or class of people by whom a product is principally used. While the manufacturer's stated intent may be relevant to an inquiry concerning the nature of the user population, the method of distribution, the availability of the product to the public and to specific groups, and the identity of purchasers or users of the product should be considered.

(6) *Other characteristics which could affect a product's safety related performance* include safety features incorporated into the product to protect against foreseeable risks that might arise during the use, handling, or storage of a product.

(d) The term *manufacturer* means any person who manufactures or imports a consumer product. (15 U.S.C. 2052(a)(4)).

[57 FR 34239, Aug. 4, 1992, as amended at 58 FR 16121, Mar. 25, 1993]

§ 1116.3 Persons who must report under section 37.

A manufacturer of a consumer product must report if:

16 CFR Ch. II (1-1-08 Edition)

(a) A particular model of the product is the subject of at least 3 civil actions filed in Federal or State Court;

(b) Each suit alleges the involvement of that particular model in death or grievous bodily injury;

(c) The manufacturer is—

(1) A party to, or

(2) Is involved in the defense of or has notice of each action prior to entry of a final order, and is involved in the discharge of any obligation owed to plaintiff under the settlement of or in satisfaction of the judgment after adjudication in each of the suits; and

(d) During one of the 24-month periods defined in § 1116.2(a), each of the three actions results in either a final settlement involving the manufacturer or in a court judgment in favor of the plaintiff.

For reporting purposes, a multiple plaintiff suit for death or grievous bodily injury is reportable if the suit involves three or more separate incidents of injury. The reporting obligation arises when at least three plaintiffs have settled their claims or when a combination of settled claims and adjudications favorable to plaintiffs reaches three. Multiple lawsuits arising from one incident involving the same product only count as one lawsuit for the purposes of section 37.

§ 1116.4 Where to report.

Reports must be sent in writing to the Commission's Office of Compliance and Enforcement, Division of Corrective Actions, Washington, DC 20207, telephone (301) 504-0608.

§ 1116.5 When must a report be made.

(a) A manufacturer must report to the Commission within 30 days after the final settlement or court judgment in the last of the three civil actions referenced in § 1116.3.

(b) If a manufacturer has filed a section 37 report within one of the 24-month periods defined in § 1116.2(a), the manufacturer must also report the information required by section 37(c)(1) for any subsequent settlement or judgment in a civil action that alleges that the same particular model of the product was involved in death or grievous bodily injury and that takes place during the same 24-month period. Each